

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the PATENT application of

Durward I. Faries, Jr. et al.

Serial No.: 10/016,128

Group Art Unit: 3767

Filed: December 17, 2001

Examiner: Witczak, Catherine

Technology Center: 3700

Confirmation No.: 4172

For: METHOD AND APPARATUS FOR HEATING SOLUTIONS WITHIN
INTRAVENOUS LINES TO DESIRED TEMPERATURES DURING
INFUSION

REPLY BRIEF

MAIL STOP APPEAL BRIEF-PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This reply brief is presented in response to the Examiner's Answer mailed August 19, 2008.

The brief is filed pursuant to the requirements of 37 C.F.R. §41.41.

(1) Status of Claims

Claims 1 - 16 and 24 - 50 have been canceled.

Claims 17, 51 and 57 are currently rejected under 35 U.S.C. §112, first paragraph, and are on appeal.

Claims 17 - 23 and 51 - 62 are currently rejected under 35 U.S.C. §103(a) and are on appeal.

(2) Grounds of Rejection to be Reviewed on Appeal

(A) Whether claims 17, 51 and 57 are unpatentable under 35 U.S.C. §112, first paragraph, as being based on a disclosure failing to comply with the written description requirement.

(B) Whether claims 17 - 23 and 51 - 62 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. 2001/0009610 (Augustine et al.) as modified by U.S. Patent No. 6,788,885 (Mitsunaga et al.) in further view of U.S. Patent No. 4,747,450 (Ikegame et al.).

(3) Argument

(A) Rejection of claims 17, 51 and 57 under the written description requirement of 35 U.S.C. §112, first paragraph

In the Office Action of October 18, 2007, the Examiner rejected claims 17, 51 and 57 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Initially, independent claims 17, 51 and 57 each recite the features of the quantity of sections being based on providing a residence time for the fluid within the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F.

The Examiner takes the position in the Office Action of October 18, 2007 (e.g., See Office Action Page 2), that the claimed features of enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F are not described in the specification in such a way as to reasonably convey to one skilled in the relevant arts that the inventors, at the time the application was filed, had possession of the claimed invention.

As discussed in the Appeal Brief (e.g., See Appeal Brief Pages 11 - 12), the specification adequately supports these features and discloses that the (desired) fluid temperature may be predetermined or entered by a user, where the warming device heats fluid to temperatures in the approximate range of 60° F - 160° F (e.g., See Specification Page 21, lines 14 - 15).

The Examiner takes the further position in the Examiner's Answer (e.g., See Examiner's Answer Page 4) that the claimed limitation is not the same limitation which was originally filed in the specification, and further provides an example situation where a prior art document may be

applied differently to the claimed limitations and the limitations described in the specification.

However, the standard for the written description requirement is whether one skilled in the art can reasonably conclude the inventor had possession of the claimed invention. As stated in the Appeal Brief (e.g., See Appeal Brief Page 10), in order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude the inventor had possession of the claimed invention. M.P.E.P. §2163 (citing Moba, B.V. v. Diamond Automation, Inc., 66 USPQ.2d 1429, 1438 (Fed. Cir. 2003)). The Examiner's position in the Examiner's Answer that the limitations in the claims and specification are not identical, and the example situation provided by the Examiner pertaining to the different application of prior art are irrelevant, since Applicant is free to claim the invention in any desired scope, provided that the claims are **supported** by the specification.

Accordingly, the issue is not whether the limitations in the claims and specification are identical as asserted by the Examiner, but rather, whether the claimed limitations are described in the specification in sufficient detail enabling one of ordinary skill in the art to reasonably conclude that the inventor had possession of the claimed invention. In fact, the subject matter of the claim need not be described literally (i.e., using the same terms) in order for the disclosure to satisfy the written description requirement. M.P.E.P. §2163.02. As discussed above, the specification expressly recites that the warming device heats fluid to temperatures in the approximate range of 60° F - 160° F (e.g., See Specification Page 21, lines 14 - 15). Certainly, one of ordinary skill in the art would reasonably conclude from this description that the intravenous fluid warming device heats the fluid to a desired temperature within a range of 60° F - 160° F as recited in the claims.

(B) Rejection of claims 17 - 23 and 51 - 62 under 35 U.S.C. §103(a) Over the Combination of the Augustine et al. Publication, and Mitsunaga et al. and Ikegame et al. Patents

In the Office Action of October 18, 2007, the Examiner rejected claims 17 - 23 and 51 - 62 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0009610 (Augustine et al.) as modified by U.S. Patent No. 6,788,885 (Mitsunaga et al.) in further view of U.S. Patent No. 4,747,450 (Ikegame et al.).

As discussed in the Appeal Brief (e.g., See Appeal Brief Page 19), there is no apparent reason to combine the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents. In support of this position, the Appeal Brief (e.g., See Appeal Brief Page 21) demonstrates that the Augustine et al. publication discloses various manners of controlling the rate of warming of IV fluid, none of which concern a quantity of sections of the cassette providing a residence time for the warming device to heat the fluid to a desired temperature as recited in the claims.

The Examiner takes the position in the Examiner's Answer (e.g., See Examiner's Answer Page 5) that Appellant's argument provides reasoning for combining the teachings of the Augustine et al. publication and Mitsunaga et al. patent. In particular, the Examiner asserts that the Augustine et al. publication discloses various manners of controlling the rate of warming of IV fluid. The Examiner further asserts that since the Augustine et al. publication does not teach the criticality of one particular mode of warming IV fluid, and since the Mitsunaga et al. patent teaches that it is known to vary tubing length to provide a residence time for warming fluid to a desired temperature, it would be obvious to use the Mitsunaga et al. patent teaching of warming fluid as one of the various manners of controlling the rate of warming of IV fluid in the Augustine et al. device.

However, the Examiner's interpretation of Appellant's arguments is mistaken. Appellant's point is that the inventors of the Augustine et al. device investigated and selected particular different modes of controlling the IV fluid warming, **and specifically excluded the manner in the Mitsunaga et al. patent** (which the Examiner asserts was well known). This is basically a form of teaching away from the claimed invention, thereby providing a showing of non-obviousness.

In further support of the lack of an apparent reason to combine the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents, the Appeal Brief (e.g., See Appeal Brief Pages 20 - 21) discusses the improper operation in a warming unit of a cassette resulting from the combination of the Augustine et al. publication and Mitsunaga et al. patent.

The Examiner takes the position in the Examiner's Answer (e.g., See Examiner's Answer Page 5) with respect to this argument that the test for obviousness does not rest on the bodily incorporation of features from a secondary reference into the structure of the primary reference, nor that the claimed invention must be expressly suggested in any one or all of the references. Rather, the Examiner claims that the test for obviousness pertains to what the combined teachings of the references would have suggested to those of ordinary skill in the art.

However, as discussed in the Appeal Brief (e.g., See Appeal Brief Page 13), the Supreme Court in KSR Int'l Co. v. Teleflex, Inc., 82 U.S.P.Q.2d 1385, 1395 (2007) provided the manner to determine obviousness. The Supreme Court indicated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than produce predictable results. Since the claimed subject matter may involve more than a simple substitution of one known element for another or the mere application of a known technique to the prior art, it will often be

necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed. **This analysis should be made explicit (by the Examiner).** The Court further noted that a patent composed of several elements is not proved obvious merely by showing that each of its elements was, independently, known in the prior art. *Id.* at 1396.

The Appeal Brief (e.g., See Appeal Brief Pages 19 - 20 and 23) expressly applies the above factors prescribed by the Supreme Court to show the claimed invention is non-obvious. In particular, the Appeal Brief (e.g., See Appeal Brief Page 21) states that the improper operation of the resulting cassette provides an indication that the claimed invention is more than a predictable use of the combination of elements proposed by the Examiner.

In addition, the Appeal Brief (e.g., See Appeal Brief Page 20) expressly states that the improper operation is specifically related to the factor of interrelated teachings of multiple patents specified by the Supreme Court, and weighs against combining the Augustine et al. publication and Mitsunaga et al. patent. The remaining factors discussed above are addressed in the Appeal Brief (e.g., See Appeal Brief Page 23) in accordance with the Supreme Court decision and demonstrate that the claimed invention is non-obvious over the combination proposed by the Examiner. Although the Supreme Court mandated that this type of analysis should be made explicit, the analysis of each of the above prescribed factors is apparently absent from the rejections in the Office Action (and from the Examiner's Answer).

The Appeal Brief (e.g., See Appeal Brief Pages 21 - 23) further asserts that no apparent reason exists to combine the Ikegame et al. patent with the Augustine et al. publication and Mitsunaga et al. patent.

The Examiner takes the position in the Examiner's Answer (e.g., See Examiner's Answer Pages 5 - 6) that all three of these documents are related to each other, as all of the documents deal in a broad sense with the problem of heating. The Examiner further asserts that although the Ikegame et al. patent is drawn to a device for cooling semiconductors, it nonetheless deals with the art of heating/cooling, and thus is relevant to the teachings of the Augustine et al. publication and Mitsunaga et al. patent.

However, the Appeal Brief follows the above analysis prescribed by the Supreme Court. The indication in the Appeal Brief (e.g., See Appeal Brief Pages 20 - 21) that the cited patent documents are directed toward diverging subject matter relates to the factor prescribed by the Supreme Court of interrelated teachings of multiple patents, and weighs against a finding of obviousness.

Further, the Examiner has failed to address in the Examiner's Answer the glaring deficiencies in the obviousness analysis required for the rejections in the Office Action. Specifically, the Examiner indicated in the Office Action (e.g., See Office Action Page 3) that altering the structure of the modified Augustine et al. device to include the configuration of the Ikegame et al. heat sink would allow for even temperature distribution without the creation of thermal stress.

However, as discussed in the Appeal Brief (e.g., See Appeal Brief Page 22), the Examiner's reasons for altering the modified Augustine et al. device with the configuration of the Ikegame et al. heat sink are misplaced. In particular, the Ikegame et al. patent discloses that the thermal stress is

created in the semiconductor element being cooled (e.g., See Column 3, lines 26 - 32). Since the Augustine et al. cassette is not utilized as a heat sink to cool an external semiconductor element, but rather, to heat fluid flowing therein within a warming device, the reduction of thermal stress on an external element appears to provide no basis for the combination proposed by the Examiner.

Moreover, the Mitsunaga et al. patent discloses that the cartridge provides regions with different fluid temperatures (e.g., See Column 4, line 56 to Column 5, line 6). Accordingly, the reason provided by the Examiner for the proposed combination (as well as the teachings of the Ikegame et al. patent) of achieving an even temperature distribution is in direct contrast to the teachings of the Mitsunaga et al. patent.

(C) Claims 20, 54 and 60 are Patentable Over the Combination of the Augustine et al. Publication and Mitsunaga et al. and Ikegame et al. Patents

Claims 20, 54 and 60 recite the features of a conductive contact disposed about a portion of the fluid line tubing (Claim 20)/fluid flow means (Claim 54)/fluid conduit (Claim 60) and detectable by the intravenous fluid warming device to indicate the presence of the cassette within the warming device and control device operation (e.g., See Fig. 2, where contact 60 is disposed around tubing section 56).

The Examiner takes the position in the Office Action (e.g., See Office Action Pages 2 - 3) that the combination of the Augustine et al. publication, and Mitsunaga et al. and Ikegame et al. patents discloses the claimed invention, and further alleges that the Augustine et al. publication discloses a conduction contact disposed about a portion of the fluid flow means to indicate the

presence of a cassette within the warming device. The Examiner further alleges in the Examiner's Answer (e.g., See Examiner's Answer Page 6) that cassette presence circuit (126) is located on the heater plate assembly (120) into which cassette (104) is inserted, and when the cassette (including the fluid line tubing) is inserted into the heater plate assembly, the presence circuit is disposed about (surrounding) the cassette fluid tubing.

The Examiner's position is respectfully traversed. In particular, the Augustine et al. publication discloses that the cassette presence circuit includes components disposed on the cassette, and in or on the housing of the warming unit (e.g., See Paragraph 0032). Presence circuit 126 comprises a magnet 128 and sensor 129 located on respective heater plates, where the cassette includes a presence indicator 153 (e.g., made from a soft ferro-magnetic material) for the cassette presence circuit that is disposed on a rail of the cassette external of the fluid flow passage (e.g., See Figs. 1 and 8; Paragraph 0030, and 0032).

Although the Examiner relies on Fig. 2, this figure does not illustrate the precise location of the presence circuit relative to the fluid passage. However, the Augustine et al. publication expressly discloses that in order for the cassette presence circuit to close to enable heating, **the presence indicator 153 must be positioned between magnet 128 and sensor 129** (e.g., See Fig. 10; and Paragraph 0033). Since the presence indicator is disposed on a rail external of the fluid passageway as discussed above, the magnet and sensor **must** similarly be disposed external of the fluid passage to properly receive the presence indicator therebetween. Accordingly, the presence circuit components (e.g., magnet, sensor and presence indicator) are disposed external of the fluid passage, as opposed to being disposed about a portion of the fluid conduit as recited in the claims.

(D) Claim 22 is Patentable Over the Combination of the Augustine et al. Publication, and Mitsunaga et al. and Ikegame et al. Patents

Claim 22 recites the fitting including a thermally conductive member disposed within the fitting and in direct contact with fluid flowing through the fitting, wherein the thermally conductive member receives the temperature sensor to measure temperature of the fluid flowing within the fluid cassette (e.g., See Fig. 4, where thermally conductive receptacle 96 is secured in projection 94 and receives temperature probe 98 to measure fluid temperature).

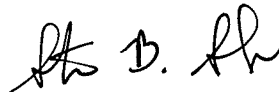
The Examiner indicates in the Office Action (e.g., See Office Action Pages 2 - 3) that the Augustine et al. publication discloses a temperature sensor. The Examiner further asserts in the Examiner's Answer (e.g., See Examiner's Answer Page 6) that the Augustine et al. publication discloses a fluid outlet port 148 that may also have an infrared thermometer, integral heat sensor, or thermocouple for sensing fluid temperature, and that other heat sensor or thermocouples may be placed at other locations in the system such as at the inlet port 146, or may be strategically located inside the fluid pathway 144.

However, the Augustine et al. publication merely discloses a fluid outlet port 148 that may receive a temperature sensor. There is no disclosure, teaching or suggestion of a thermally conductive receptacle disposed in that port in contact with the fluid, and receiving a temperature sensor within the thermally conductive receptacle as recited in the claim.

(4) Conclusion

In view of the foregoing and the reasons indicated in the Appeal Brief, it is submitted that the rejections of claims 17 - 23 and 51 - 62 are improper and, accordingly, the Board is respectfully requested to reverse the rejections and order that this application be allowed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Stuart B. Shapiro".

Stuart B. Shapiro
Registration No. 40,169

EDELL, SHAPIRO & FINNAN, LLC
1901 Research Boulevard, Suite 400
Rockville, Maryland 20850
(301) 424-3640

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